4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA-2015-M-0619]

Medical Devices; Neurological Devices; Classification of the Limited Output Transcutaneous Piezoelectric Stimulator for Skin Reactions Associated with Insect Bites

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites' classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on November 7, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Hoffman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1434, Silver Spring, MD 20993-0002, 301-796-6476, michael.hoffman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a

classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of "low-moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On September 8, 2010, Ecobrands, Ltd., submitted a request for classification of the Zap-It! under section 513(f)(2) of the FD&C Act. Subsequently, on February 14, 2013, Tecnimed S.r.l., submitted a similar request for classification of the Zanza-Click, Mini-Click, and Disc-o-Click under section 513(f)(2) of the FD&C Act. Both manufacturers recommended that the devices be classified into class II (Refs. 1 and 2).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the requests in order to classify the devices under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the requests, FDA determined that the devices can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, on November 7, 2014, FDA issued orders to both requestors classifying the devices into class II. FDA is codifying the classification of the devices by adding 21 CFR 882.5894.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites will need to comply with the special controls named in this final order. The device is assigned the generic name limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites, and it is identified as a device intended to alleviate skin reactions associated with insect bites via cutaneous, piezoelectric stimulation at the local site of the bite.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks in table 1.

Table 1.--Limited Output Transcutaneous Piezoelectric Stimulator for Skin Reactions Associated with Insect Bites Risks and Mitigation Measures

Identified Risk	Mitigation Measure
Cutaneous burns	Characterization of Electrical Output Labeling
Adverse skin reactions	Biocompatibility Assessment
Damage to sensitive tissue (e.g., eyes, lips, inside mouth, open wounds)	Labeling
Infection	Labeling
Burns and other injuries due to ignition of flammable substances which may be used in the same intended use environment (e.g., insect repellent)	Labeling
Interference with implanted devices and other patient care devices	Labeling
Failure to identify correct population and condition	Labeling
Device failure	Non-clinical (Bench) Testing Labeling

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

- Appropriate testing to characterize the electrical output specifications of the device (i.e., total charge delivered, maximum instantaneous output current, maximum instantaneous output voltage, pulse duration, charge density) must be conducted.
- Mechanical bench testing must demonstrate that the device will withstand the labeled number duration of uses.
- All elements of the device that may contact the patient must be assessed to be biocompatible.
- Labeling must include:
    - Validated instructions which addresses the following:
        - Identification of areas of the body which are appropriate and not appropriate for contact with the device;
        - whether use of the device in conjunction with flammable materials (e.g., insect repellent) is appropriate;
        - use of the device on or near implanted devices; and
        - how to identify the correct type of skin condition.
    - Technical parameters of the device (maximum output voltage (instantaneous), maximum output current (instantaneous), and pulse duration).
    - Language to direct end users to contact the device manufacturer and MedWatch if they experience any adverse events with this device.
    - The anticipated number of device uses prior to failure.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the

safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is exempt from premarket notification requirements. Persons who intend to market this type of device need not submit to FDA a premarket notification, prior to marketing the device, which contains information about the limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910-0485.

IV. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov.

1. DEN100024: De Novo Request per 513(f)(2) from Ecobrands, Ltd., dated September 8, 2010.

2. DEN130019: De Novo Request per 513(f)(2) from Tecnimed S.r.l., dated February 14, 2013.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882--NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Add § 882.5894 to subpart F to read as follows:

§ 882.5894 Limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites.

(a) Identification. A limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites is a device intended to alleviate skin reactions associated with insect bites via cutaneous, piezoelectric stimulation at the local site of the bite.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate testing to characterize the electrical output specifications of the device (i.e., total charge delivered, maximum instantaneous output current, maximum instantaneous output voltage, pulse duration, charge density) must be conducted.

(2) Mechanical bench testing must demonstrate that the device will withstand the labeled number duration of uses.

(3) All elements of the device that may contact the patient must be assessed to be biocompatible.

(4) Labeling must include:

(i) Validated instructions which addresses the following:

(A) Identification of areas of the body which are appropriate and not appropriate for contact with the device.

(B) Whether use of the device in conjunction with flammable materials (e.g., insect repellent) is appropriate.

(C) Use of the device on or near implanted devices.

(D) How to identify the correct type of skin condition.

(ii) Technical parameters of the device (maximum output voltage (instantaneous), maximum output current (instantaneous), and pulse duration).

(iii) Language to direct end users to contact the device manufacturer and MedWatch if they experience any adverse events with this device.

(iv) The anticipated number of device uses prior to failure.

Dated: March 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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